SEP 20 2012

ORTHOFIX

**510(k) Summary**
**[as required by 21 CFR 807.92(c)]**

## Orthofix Contours Proximal Humeral Plate (PHP)

**510(k) _K122541**

**1. Submitted by:**

Orthofix Srl
Via delle Nazioni 9
37012 Bussolengo (VR)
Italy

Registration number 9680825

Contact Person
Elena Varini
International Orthopedics Regulatory Manager
Telephone: +39 (045) 671 9000
Facsimile: +39 (045) 671 9380

Date Prepared September 17, 2012

**2. Device Name:**

| | |
|---|---|
| Trade/Proprietary Name | Orthofix Contours Proximal Humeral Plate (PHP) |
| Common Name | Bone plate |
| Device Classification | 87 KTW (21 CFR 888.3030) Single/multiple component metallic bone fixation appliances and accessories. |

**3. Predicate Device:**

The Orthofix Contours Proximal Humeral Plate (PHP) is substantially equivalent to the Orthofix Titanium Humeral Plating System, "LSP", K062920

**4. Intended Use:**

The Orthofix Contours Proximal Humeral Plate (PHP) is intended for fractures, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

## 5. Description:

This Special 510(k) is being supplied to the U.S. FDA to provide authorization to market the device Orthofix Contours Proximal Humeral Plate (PHP) for interstate commerce. The Orthofix Contours Proximal Humeral Plate (PHP) is a modified version of the Orthofix Titanium Humeral Plating System "LSP", cleared under 510(k) K062920.

Like the predicate device, the Orthofix Contours Proximal Humeral Plate (PHP) is a locking titanium plate intended for the treatment of fractures, osteotomies and non-unions of the proximal humerus.

The Orthofix Contours Proximal Humeral Plate (PHP) consists of a left and a right plate that has to be used in combination with at least two Diaphyseal Screws, a main locking screw and at least two titanium hexagonal Fine Threaded Screws. In addition titanium/polymeric cerclage wires can be used to achieve further stabilization of the bone fragments.

Instrumentation is available for the insertion of the plates and screws.

The modifications introduced with the Orthofix Contours Proximal Humeral Plate (PHP) are summarized below:

- Dimensional changes, concerning width and central part height of the plate, diameter of some fixation points and lengths of the revision screws.

- Sterilization configuration: Orthofix Contours Proximal Humeral Plate (PHP) will be sold in a sterile configuration while the predicate device, Orthofix Titanium Humeral Plating System "LSP" is sold in a non-sterile configuration.

- Packaging configuration: as the Orthofix Contours Proximal Humeral Plate (PHP) will be sold in a sterile configuration, the packaging will be modified with respect to the predicate device.

## 6. Substantial equivalence:

Documentation is provided which demonstrates the Orthofix Contours Proximal Humeral Plate (PHP) to be substantially equivalent to other legally marketed devices. The Orthofix Contours Proximal Humeral Plate (PHP) and the predicate device Orthofix Titanium Humeral Plating System "LSP" are bone plates as defined in 21 CFR 888.3030, furthermore, the size, shape and materials for the subject devices are comparable to the predicate devices.

Testing in accordance with ASTM F384-06 and ASTM F382-99 shows the mechanical strength of the Orthofix Contours Proximal Humeral Plate (PHP) to be equivalent or better than the predicate devices.

## 7. Conclusion:

Based upon the similarities in design, materials and intended uses, it is concluded that the Orthofix Contours Proximal Humeral Plate (PHP) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Orthofix SRL
% Ms. Candace Cederman
Consultant
22423 Skyview Drive
West Linn, Oregon 97068

Re: K122541
Trade/Device Name: Orthofix Contours Proximal Humeral Plate (PHP)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTW
Dated: August 20, 2012
Received: August 21, 2012

Dear Ms. Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122541

Device Name: Orthofix Contours Proximal Humeral Plate (PHP)

Indications for Use:

The Orthofix Contours Proximal Humeral Plate (PHP) is intended for fractures, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122541